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FORM PTO-1449

U.S. Dept of Commerce
Patent and Trademark Office

Atty Docket No.

P1089R1C1

Serial No.

09/724,868

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Lam et al.

Filing Date

28 Nov 2000

Group

Unassigned 1644

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
MO	* 1	4,093,606	06.06.78	Coval, M.			
	* 2	4,457,916	03.07.84	Hayashi et al.			
	* 3	4,499,073	12.02.85	Tenold, R.			
	* 4	4,877,608	31.10.89	Lee, T. et al.			
	* 5	4,940,782	10.07.90	Rup et al.			
	* 6	5,032,405	16.07.91	Huang, H. et al.			
	* 7	5,036,049	30.07.91	Audhya, T. et al.			
	* 8	5,096,885	17.03.92	Pearlman et al.			
	* 9	5,147,637	15.09.92	Wright et al.			
	*10	5,149,653	22.09.92	Roser			
	*11	5,215,743	01.06.93	Singh, M. et al.			
	*12	5,262,296	16.11.93	Ogawa, E. et al.			
	*13	5,307,640	03.05.94	Fawzy et al.			
	*14	5,399,670	21.03.95	Bhattacharya, P. et al.			
	*15	5,506,342	09.04.96	Reno et al.			
	*16	5,580,856	03.12.96	Prestrolski et al.			
	*17	5,589,167	31.12.96	Cleland et al.			
	*18	5,608,038	04.03.97	Eibl et al.			
	*19	5,654,403	05.08.97	Smith et al.			
	*20	5,730,980	24.03.98	Olevitch et al.			
	*21	5,736,137	07.04.98	Anderson et al.			
	*22	5,770,700	23.06.98	Webb et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
MO	*23	AU-B-30771/89	07.09.89	AUSTRALIA				
	*24	2,138,853	29.06.95	CANADA				
	*25	303,746	22.02.89	EPO				
	*26	391,444	10.10.90	EPO				
	*27	661,060	05.07.95	EPO (WITH ENGLISH ABSTRACT)				
	*28	WO 89/09402	05.10.89	PCT (WITH ENGLISH ABSTRACT)				
	*29	WO 89/11297	30.11.89	PCT				
	*30	WO 90/11091	04.10.90	PCT				
	*31	WO 92/22653	23.12.92	PCT				
	*32	WO 94/11026	26.05.94	PCT				
	*33	WO 94/26302	24.11.94	PCT				

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5/29/04

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FORM PTO-1449	U.S. Dept. of Commerce Patent and Trademark Office	Atty Docket No. P1089R1C1	Serial No. 09/724,868
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)		Applicant Lam et al.	
		Filing Date 28 Nov 2000	Group Unassigned 644

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
MD	*34	WO 96/41164	19.12.96	PCT				
MD	*35	WO 97/04801	13.02.97	PCT				
	*36	WO 97/04807	13.02.97	PCT				
MD	*37	WO 97/17087	15.05.97	PCT				

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

MD	*38	Akers, M., "Considerations in selecting antimicrobial preservative agents for parenteral product development." <u>Pharmaceutical Technology</u> pps. 36-40/43-44:46 (May 1984)
	*39	Albelda et al., "Integrins and other cell adhesion molecules" <u>FASEB J</u> 4(11):2868-2880 (1990)
	*40	Arakawa et al., "Protein-Solvent Interactions in Pharmaceutical Formulations" <u>Pharmaceutical Research</u> 8(3):285-291 (1991)
	*41	Bam et al., "Stability of Protein Formulations: Investigation of Surfactant Effects by a Novel EPR Spectroscopic Technique" <u>Pharm. Res.</u> 12:2-11 (1995)
	*42	Bhanuvala et al., "Both Glassy State and Native Structure are Required for Storage Stability of Lyophilized Interleukin-1 Receptor Antagonist." <u>Pharm. Res.</u> (Abstract #2007) 12(9):S-80 (1995)
	*43	Hogard et al., "Practical considerations in the production, purification, and formulation of monoclonal antibodies for immunoscintigraphy and immunotherapy" <u>Seminars in Nuclear Medicine</u> 19(3):202-220 (1989)
	*44	Chang and Fischer, "Development of an Efficient Single-Step Freeze-Drying Cycle for Protein Formulations" <u>Pharm. Res.</u> 12(6):831-837 (1995)
	*45	Chang et al., "Development of a Stable Freeze-dried Formulation of Recombinant Human Interleukin-1 Receptor Antagonist" <u>Pharmaceutical Research</u> 13(2):243-248 (1996)
	*46	Chang et al., "Nucleotide sequence of the alkaline phosphatase gene of <i>Escherichia coli</i> " <u>Gene</u> 44:121-125 (1986)
	*47	Clark et al., "Lability of Asparagine and Aspartic Acid Residues in Proteins and Peptides" <u>Stability of Protein Pharmaceuticals. Part A: Chemical and Physical Pathways of Protein Degradation</u> , T.J. Ahern and M.C. Manning, New York: Plenum Press, Chapter 1, pps. 1-29 (1992)
	*48	Cleland and Jones, "Development of Stable Protein Formulations for Microencapsulation in Biodegradable Polymers" <u>Proced. Intern. Symp. Control. Rel. Biact. Mater.</u> 22:514-515 (1995)
	*49	Cleland et al., "Mechanisms of Nonionic Surfactant Stabilization of Proteins" <u>Pharmaceutical Research</u> (Abstract #BIOTEC 2012; Ninth Annual Meeting of the American Association of Pharmaceutical Scientists held in San Diego, CA on November 6-10, 1994) 11(10 Suppl.):S73 (1994)
	*50	Cleland et al., "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation, and Oxidation" <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> 10(4):307-377 (1993)
	*51	Drabor et al., "Stability of Monoclonal IgM Antibodies Freeze-Dried in the Presence of Trehalose" <u>Journal of Immunological Methods</u> 181(1):37-43 (1995)
	*52	Hernandez et al., "Role of neutrophils in ischemia-reperfusion-induced microvascular injury" <u>Am. J. Physiol.</u> 253(3 Pt. 2):H699-H703 (1987)
MD	*53	Mildreth et al., "A Human Lymphocyte-associated Antigen Involved in Cell-mediated Lympholysis" <u>European Journal of Immunology</u> 13:202-208 (1983)

Examiner

Date Considered

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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

MD	*54	Hildreth et al., "The human lymphocyte function-associated (HLFA) antigen and a related macrophage differentiation antigen (HMac-1): functional effects of subunit-specific monoclonal antibodies" <u>Immunol.</u> 134:3272-3280 (1985)
	*55	Hynes, "Integrins: versatility, modulation, and signaling in cell adhesion" <u>Cell</u> 69(1):11-25 (1992)
	*56	Izutsu et al., "The effects of additives on the stability of freeze-dried β -galactosidase stored at elevated temperature" <u>Int'l. J. Pharmaceutics</u> 71:137-146 (1991)
	*57	Ustila et al., "Inflammation-induced endothelial cell adhesion to lymphocytes, neutrophils, and monocytes" <u>Transplantation</u> 48(5):727-731 (1989)
	*58	Konradiakoff, A.A., "Tertiary Structure Is a Principal Determinant to Protein Denaturation" <u>Science</u> 240:191-194 (1988)
	*59	Lam et al., "Microencapsulation of Recombinant Humanized Monoclonal Antibody for Local Delivery" <u>American Association of Pharmaceutical Scientists, Western Regional Meeting, South San Francisco, CA</u> (Abstract #P-22 and poster presented at the meeting) (April 24-25, 1997)
	*60	Lam et al., "Microencapsulation of Recombinant Humanized Monoclonal Antibody for Local Delivery" <u>Proceedings of the 24th International Symposium on Controlled Release of Bioactive Materials</u> 24:759-760 (June 15-19, 1997)
	*61	Lam et al., "Pitfalls in Development of Multi-Dose Liquid Formulations for Three Protein Pharmaceuticals" <u>ACS National Meeting, New Orleans</u> (Abstract #137 and slides presented) (March 24-28, 1996)
	*62	Li et al., "Aggregation and Precipitation of Human Relaxin Induced by Metal-Catalyzed Oxidation" <u>Biochemistry</u> 34(17):5762-5772 (1995)
	*63	Monning et al., "Stability of Protein Pharmaceuticals" <u>Pharm. Res.</u> 6(11):903-918 (1989)
	*64	Miloski et al., "Inhibition of CD18-dependent neutrophil adherence reduces organ injury after hemorrhagic shock in primates" <u>Surgery</u> 108:206-212 (1990)
	*65	Nielsen, et al., "Stability of Freeze Dried Horseradish Peroxidase Conjugated Monoclonal Antibodies Used in Diagnostic Serology" <u>Journal of Immunoreassay</u> 16(2):183-197 (1995)
	*66	Novak et al., "The tolerance and safety of intravenously administered benzyl alcohol in methylprednisolone sodium succinate formulations in normal human subjects" <u>Toxicology and Applied Pharmacology</u> 23(1):54-61 (Sep 1972)
	*67	Parfitt et al., "Analysis of Protein Drugs" <u>Peptide and Protein Drug Delivery</u> , Vincent H. L. Lee, Marcel Dekker, Inc., Chapter 6, pps. 247-301 (1991)
	*68	Picken et al., "Nucleotide sequence of the gene for heat-stable enterotoxin II of <i>Escherichia coli</i> " <u>Infection and Immunity</u> 42(1):269-275 (1983)
	*69	Pikal et al., "The Effects of Formulation Variables on the Stability of Freeze-Dried Human Growth Hormone" <u>Pharm. Res.</u> 8:427-436 (1991)
	*70	Pikal, M., "Freeze-Drying of Proteins, Part 2: Formulation Selection" <u>BioPharm.</u> 3(9):26-30 (1990)
	*71	Rao and Kroon, "Orthoclone OKT3: Chemical Mechanisms and Functional Effects of Degradation of a Therapeutic Monoclonal Antibody" <u>Stability and Characterization of Protein and Peptide Drugs: Case Histories</u> , eds. John Wang and Rodney Pearlman, New York: Plenum Press pps. 135-158, chapter 4, (1993)
✓	*72	Reilly et al., "Oral delivery of antibodies: future pharmacokinetic trends" <u>Clin. Pharmacokinet.</u> 32(4):313-323 (1997)
MD	*73	Sapan, "Immunoglobulin stability" <u>Biotechnol. Appl. Biochem.</u> 25:9-12 (1997)

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